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IN THE

Supreme Court of the United States

DONNA S. RIEGEL, individually and as administrator of the estate of Charles R. Riegel,

Petitioner,

v.

MEDTRONIC, INC.,

Respondent.

On Writ Of Certiorari To The United States Court Of Appeals For The Second Circuit

BRIEF FOR RESPONDENT

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QUESTION PRESENTED

Whether the express preemption provision of the Medical Device Amendments to the Food, Drug, and Cosmetic Act, 21 U.S.C. § 360k(a), preempts state-law claims seeking damages for injuries caused by medical devices that received premarket approval from the Food and Drug Administration.

RULE 29.6 STATEMENT

The corporate disclosure statement included in the brief in opposition to the petition for a writ of certiorari remains accurate.

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Gregory J. Scandaglia & Therese L. Tully, *Express Preemption and Premarket Approval Under the Medical Device Amendments*, 59 Food & Drug L.J. 245 (2004) 5

BRIEF FOR RESPONDENT

Respondent Medtronic, Inc., respectfully submits that the judgment of the court of appeals should be affirmed.

STATEMENT

Petitioner is asserting state-law products liability claims challenging the design, manufacturing, and labeling of Medtronic's Evergreen Balloon Catheter, a life-saving medical device that the federal Food and Drug Administration ("FDA") found to be safe and effective after a thorough examination pursuant to its Premarket Approval ("PMA") process. Petitioner contends that a lay jury should be permitted to second-guess the FDA's expert determination regarding the Evergreen Balloon Catheter's safety and effectiveness because the PMA process at issue in this case is purportedly "similar to" the § 510(k) notification process (Pet. Br. 13), which this Court held not to have preemptive effect in *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996). Petitioner's characterization of the PMA process—and its preemptive force—is deeply flawed.

As this Court recognized in *Lohr*, the streamlined "§ 510(k) notification process is by no means comparable to the PMA process." 518 U.S. at 478-79. Whereas § 510(k) review entails no substantive evaluation of a device's safety and effectiveness (*id.* at 479), the PMA process requires manufacturers to "submit detailed information regarding the safety and efficacy of their devices," which the FDA spends hundreds of hours reviewing. *Id.* at 477. For devices that the FDA finds to be safe and effective, that "rigorous" process culminates in a set of device-specific design, manufacturing, and labeling requirements to

which the manufacturer must adhere in order to market its device. *Id.*

The Second Circuit held that petitioner's state-law claims "would, if successful, impose state requirements that differed from, or added to, the PMA-approved standards" established by the FDA, and are therefore expressly preempted by 21 U.S.C. § 360k(a). Pet. App. 32a. This conclusion is consistent with the plain language of Section 360k(a) and this Court's preemption analysis in *Lohr*. It also furthers the important legislative objectives that animate Section 360k(a)—which Congress enacted to prevent States from undermining the uniform federal regulatory framework that governs medical devices and from disturbing the FDA's expert regulatory judgments regarding the safety and effectiveness of such devices.

A. Regulatory Background

1. Until 1976, the FDA generally lacked authority to regulate medical devices. That year, Congress enacted the Medical Device Amendments ("MDA") to the federal Food, Drug, and Cosmetic Act ("FDCA"), which extended the FDA's regulatory authority to medical devices. Pub. L. No. 94-295, 90 Stat. 539.

In enacting the MDA, Congress sought to ensure that safe and effective medical devices would be readily available to treat patients in need of life-saving care. To that end, Congress crafted a regulatory framework that struck a careful balance between regulation and innovation. The MDA therefore "provide[s] for the safety and effectiveness of medical devices" (90 Stat. 539), while simultaneously "encourag[ing] the[ ] research and development" of "sophisticated, critically important" devices. S. Rep. No. 33, 94th Cong., 2d Sess. 2 (1975); *see also* H.R.

Rep. No. 853, 94th Cong., 2d Sess. 12 (the MDA "reflects the need to develop innovative new devices, consistent with the need to protect the subjects of device research").

The MDA establishes three classes of medical devices. 21 U.S.C. § 360c. Class I devices, such as tongue depressors, are devices for which the generally applicable design, manufacturing, and labeling standards established by the MDA "are sufficient to provide reasonable assurance of . . . safety and effectiveness." *Id.* § 360c(a)(1)(A)(i). Class II devices, such as hearing aids, are devices for which the "general controls" applicable to all devices are insufficient to provide a reasonable assurance of safety and effectiveness. *Id.* § 360c(a)(1)(B). Although such devices may be marketed without advance approval from the FDA, they must comply with additional federal performance regulations known as "special controls." *Id.* Class III devices, such as pacemakers, are those devices that either "present[ ] a potential unreasonable risk of illness or injury" or that are "represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health," and for which neither general nor special controls would be sufficient to provide a reasonable assurance of safety and effectiveness. *Id.* § 360c(a)(1)(C).

The MDA provides that, before a Class III medical device can be marketed, it must be examined by the FDA through the rigorous PMA process and found to present a reasonable assurance of safety and effectiveness. 21 U.S.C. § 360c(a)(1)(C). As this Court recognized in *Lohr*, however, "[n]ot all, nor even most, Class III devices on the market today have received premarket approval because of two important exceptions to the PMA requirement." 518

U.S. at 477. First, the MDA permits medical devices that were commercially available before the statute's effective date to remain on the market until the FDA issues regulations requiring such devices to undergo the PMA process—a step that the FDA has taken for few pre-MDA devices. *Id.* at 478; *see also* 21 U.S.C. § 360e(b)(1)(A).

Second, the MDA provides that newly developed devices that are "substantially equivalent" to pre-MDA devices need not be approved under the PMA process in the absence of FDA regulations requiring PMA review. 21 U.S.C. § 360e(b)(1)(B). Those devices need only undergo a "limited form of review" known as the § 510(k) notification process, which requires the manufacturer to submit a report notifying the FDA of its intention to market a new device. *Lohr*, 518 U.S. at 478. The overwhelming majority of new Class III medical devices that reach the market do so through the § 510(k) notification process. Indeed, in fiscal year 2005, the FDA received 3130 § 510(k) notifications, but only 43 original PMA applications. *See* FDA Office of Device Evaluation, Annual Report Fiscal Year 2005, at 26, *at* www.fda.gov/cdrh/annual/fy2005/ode/report.pdf [hereinafter FDA, 2005 Annual Report].[1]

The FDA's review under the § 510(k) notification process is limited to whether the device is "substantially equivalent" to a pre-MDA device and does not extend to the device's safety or effectiveness. The

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[1] Congress has nevertheless expressed a strong preference for use of the PMA process, rather than the § 510(k) notification process, to introduce new medical devices. *See* Safe Medical Devices Act of 1990, Pub. L. No. 101-629, 104 Stat. 4511 (requiring *all* Class III devices eventually to undergo PMA review).

FDA spends an average of only twenty hours reviewing a § 510(k) notification report (*Lohr*, 518 U.S. at 479), and approves nearly ninety percent of such submissions. FDA, 2005 Annual Report 36. In contrast, the FDA spends an average of 1200 hours reviewing a PMA submission (*Lohr*, 518 U.S. at 477), and approves less than sixty percent of such applications. FDA, 2005 Annual Report 36.

2. Class III devices that are not substantially equivalent to a pre-MDA device are not eligible for the § 510(k) notification process and must undergo PMA review. "PMA is the most stringent type of device marketing application required by FDA." FDA, Device Advice—Premarket Approval (PMA) 1, *at* http://www.fda.gov/cdrh/devadvice/pma/printer.html [hereinafter FDA, Premarket Approval]. During the PMA process, the FDA undertakes an extensive review of clinical studies and medical literature regarding the device, and a thorough examination of the device's design, manufacturing, and labeling to determine whether the device is safe and effective and therefore appropriate for marketing. 21 U.S.C. § 360e(d)(2). "PMA approval is based on a determination by FDA that the PMA [application] contains sufficient valid scientific evidence to assure that the device is safe and effective for its intended use(s)." FDA, Premarket Approval 1.

In contrast with a § 510(k) notification, which "'requires little information, rarely elicits a negative response from the FDA, and gets processed very quickly'" (*Lohr*, 518 U.S. at 479), the PMA process is "extensive, time-consuming, and expensive," and consumes vast amounts of financial and human resources for both the device manufacturer and the FDA. Gregory J. Scandaglia & Therese L. Tully, *Express Preemption and Premarket Approval Under the*

Medical Device Amendments, 59 Food & Drug L.J. 245, 245 (2004). Submission of a PMA application to the FDA is generally preceded by years of painstaking research and development by the device manufacturer. The application that the manufacturer eventually submits to the FDA "involves many volumes of materials" that "include device description and intended use, nonclinical and clinical studies, case report forms, manufacturing methods, [and] labeling." FDA, Premarket Approval 18. The PMA application must include a "complete description" of the device; a "complete description" of the "methods used in . . . [its] manufacture, processing, packing, [and] storage"; the results of nonclinical studies with the device, including microbiological, toxicological, stress, wear, and shelf life; the results of clinical investigations involving human subjects, including safety and effectiveness data, adverse reactions and complications, and device failures and replacements; a bibliography of all published reports regarding the device's safety and effectiveness; and copies of all proposed labeling for the device. 21 C.F.R. § 814.20(b)(4); *see also* FDA, Premarket Approval 21-24. As part of the PMA process, the FDA may refer the application to an advisory panel of outside experts for consideration and a recommended disposition; all applications for first-of-a-kind devices are submitted to such a panel. 21 C.F.R. § 814.44; *see also* FDA, Premarket Approval 7.

The FDA issues an approval order for a device if it finds that there is a reasonable assurance of safety and effectiveness when the device is designed, manufactured, and labeled in accordance with the specifications of its PMA application. 21 U.S.C. § 360e(d)(1)(A)(i); *id.* § 360e(d)(2). The approval order authorizes the manufacturer to market the de-

vice in accordance with those design, manufacturing, and labeling specifications. J.A. 16. The order is accompanied by a set of Conditions of Approval that require the manufacturer to submit a PMA supplement for any changes to the device that affect its safety and effectiveness, and that prohibit the manufacturer from marketing the modified device before obtaining FDA approval of the supplemental application. 21 U.S.C. § 360e(d)(6)(A)(i).

In developing this comprehensive regulatory framework for medical devices, Congress recognized that state-law requirements could undermine the public health by imposing overlapping and potentially irreconcilable obligations on device manufacturers and by displacing the FDA's expert regulatory judgments regarding a device's safety and effectiveness. Congress therefore included Section 360k(a) in the MDA as a "general prohibition on non-Federal regulation" of medical devices. H.R. Rep. No. 853, 94th Cong., 2d Sess. 45 (1976). That provision expressly preempts state-law requirements applicable to medical devices that are "different from, or in addition to," requirements established by the FDA. 21 U.S.C. § 360k(a).

In *Lohr*, this Court held that Section 360k(a) did not expressly preempt state-law products liability claims regarding a pacemaker that had entered the market through the § 510(k) notification process. In so holding, the Court took great pains to distinguish the "limited form of review" of the § 510(k) notification process from the "rigorous" scrutiny of the PMA process. *Lohr*, 518 U.S. at 478.

B. Proceedings Below

1. Medtronic's Evergreen Balloon Catheter is a Class III medical device that underwent the FDA's

PMA process. Medtronic developed the device for use by licensed physicians to open the clogged arteries of patients suffering from coronary disease. Pet. App. 3a. During an angioplasty procedure, the catheter is inserted into the artery, inflated with saline solution, and then deflated once the procedure is complete. *Id.*

After reviewing the device specifications and clinical and nonclinical studies that Medtronic submitted as part of its PMA application, the FDA found that the Evergreen Balloon Catheter is safe and effective for its intended use when it is designed, manufactured, and labeled in accordance with the specifications of its PMA application. J.A. 16. The Conditions of Approval attached to the PMA approval letter required that "[b]efore making any change affecting the safety or effectiveness of the device," Medtronic "submit a PMA supplement for review and approval by FDA." *Id.* at 20. "Failure to comply with the conditions of approval," the FDA cautioned, "invalidates this approval order" and constitutes a "violation of the Federal Food, Drug, and Cosmetic Act." *Id.* at 16.

After receiving PMA approval, Medtronic designed, manufactured, and labeled the Evergreen Balloon Catheter in accordance with the specifications set forth in its PMA application, and did not modify the device until the FDA had approved the requisite PMA supplement. J.A. 18, 26.

The Evergreen Balloon Catheter was used during an angioplasty procedure to treat Charles Riegel's "diffusely diseased" and "heavily calcified" right coronary artery. Pet. App. 4a. The treating physician elected to use the Evergreen Balloon Catheter after his attempts to use other devices, including

other catheters, had proved unsuccessful. The physician selected the Evergreen Balloon Catheter even though the labeling of the device clearly states that it should not be used in patients, such as Mr. Riegel, who have "diffuse or calcified stenoses." *Id.* After inserting the Evergreen Balloon Catheter into Mr. Riegel's artery, the physician inflated the device several times, up to a pressure of ten atmospheres—again directly contravening the device's label, which warns that it should not be inflated beyond eight atmospheres. *Id.* On the final inflation, the device burst, seriously injuring Mr. Riegel. *Id.*

2. Petitioner filed this diversity action against Medtronic in the United States District Court for the Northern District of New York, alleging state-law claims for negligent design, testing, inspection, manufacture, distribution, labeling, marketing, and sale of the Evergreen Balloon Catheter; strict liability; and breach of express and implied warranty. Pet. App. 4a-5a.

The district court granted Medtronic summary judgment on petitioner's negligence, strict liability, and implied warranty claims on the ground that those claims were expressly preempted by 21 U.S.C. § 360k(a).[2]

3. The Second Circuit affirmed. Applying the plain language of Section 360k(a), as construed by this Court in *Lohr*, the court held that petitioner's products liability claims, if successful, would impose

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[2] The district court later granted summary judgment to Medtronic on petitioner's remaining negligent manufacturing and express warranty claims on grounds other than preemption, and those claims are no longer at issue in this case. Pet. App. 90a.

specific state-law "requirements" that would be "different from, or in addition to," the device-specific requirements that the FDA established for the Evergreen Balloon Catheter through its PMA approval order.

The Second Circuit surveyed the features of the "lengthy and rigorous" PMA process (Pet. App. 8a), and concluded that the Evergreen Balloon Catheter and other PMA-approved devices "are subject to federal device-specific requirements." *Id.* at 25a. The court reasoned that, unlike the § 510(k) process, "PMA approval explicitly signifies the FDA's substantive approval of the device's reasonable safety and effectiveness." *Id.* at 27a. Because "the manufacturer cannot make any changes that might affect the safety and effectiveness of the device without further FDA approval," the court continued, a PMA-approved device "is clearly subject to the federal, device-specific requirement of adhering to the standards contained in its individual, federally approved PMA." *Id.* at 26a.

Turning to the state side of the preemption framework, the Second Circuit emphasized that, "[i]n *Lohr*, . . . five justices . . . endorsed the view that § 360k(a)'s reference to state 'requirements' encompassed state common law tort lawsuits." Pet. App. 30a. The court concluded that, "if successful," petitioner's state-law claims would therefore "impose state requirements" regarding the design, manufacturing, and labeling of the Evergreen Balloon Catheter that "differed from, or added to, the PMA-approved standards" for the device. *Id.* at 32a. "[S]uch a situation," the court explained, "would be quite analogous to the hypothetical situation posed by Justice Breyer in his *Lohr* concurrence, in which, notwithstanding a federal requirement for a 2-inch

hearing wire in a particular hearing aid, a plaintiff brought a tort claim relating to the same hearing aid that premised liability on the manufacturer's failure to use a wire that was 1-inch or less." *Id.* at 33a.

The Second Circuit emphasized that its "finding of preemption is consistent" with both Congress's objective in enacting the MDA "to ensure that innovations in medical device technology are not stifled by unnecessary restrictions" (Pet. App. 34a (internal quotation marks omitted)) and with the "FDA's recent determination that preemption is warranted with respect to this universe of cases." *Id.* at 37a. The court also explained that the "scope of [its] decision is . . . quite limited" because the "vast majority of Class III medical devices enter the market pursuant to the § 510(k) process" and this Court "has already held in *Lohr* that tort claims as to § 510(k)-cleared devices are not preempted." *Id.* at 36a.

SUMMARY OF ARGUMENT

Petitioner's claims seek to impose state "requirements" "with respect to" the design, manufacturing, and labeling of the Evergreen Balloon Catheter that are "different from" and in "addition to" the device-specific federal requirements established by the Evergreen Balloon Catheter's PMA approval order. These claims are therefore expressly preempted by Section 360k(a).

I. The Second Circuit correctly determined that the PMA process imposes device-specific federal requirements on medical devices.

A. Unlike the streamlined § 510(k) notification process, the rigorous PMA procedure involves a substantive evaluation of a device's safety and effectiveness. The FDA grants PMA approval only if it determines that a device is safe and effective when de-

signed, manufactured, and labeled in accordance with the specifications of its PMA application. Because a manufacturer is prohibited from modifying a PMA-approved device in a manner that could impact its safety or effectiveness, the design, manufacturing, and labeling specifications set forth in the PMA application and approved by the FDA constitute a set of federal device-specific requirements with which a PMA-approved device, such as the Evergreen Balloon Catheter, must comply.

B. This Court's holding in *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), and the FDA's regulatory framework support the conclusion that PMA approval has preemptive effect. In *Lohr*, the only manufacturing and labeling requirements applicable to the § 510(k)-cleared device were the generic FDA manufacturing and labeling regulations that are applicable to all medical devices. The Evergreen Balloon Catheter, in contrast, is subject not only to those generic requirements but also to the device-specific manufacturing and labeling requirements set forth in the FDA-approved PMA application. Similarly, the FDA regulations on which petitioner relies do not suggest that only device-specific FDA regulations can have preemptive effect, but instead demonstrate that both "specific counterpart regulations" *and* "specific requirements"—such as the device-specific requirements established by PMA approval—can give rise to preemption. 21 C.F.R. § 808.1(d).

II. The Second Circuit also correctly held that petitioner's claims seek to impose specific state-law "requirements" on the Evergreen Balloon Catheter.

A. A majority of this Court held in *Lohr* that state common-law claims constitute "requirements" within the meaning of Section 360k(a). This conclu-

sion is consistent with this Court's unbroken line of decisions holding that the term "requirement" encompasses common-law claims when used in a preemption provision. *See Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 521 (1992) (plurality op.); *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 443 (2005). Petitioner's argument that Section 360k(a) does not preempt *any* state common-law claims is therefore squarely foreclosed by precedent.

Moreover, nothing in the language or legislative history of the MDA supports a contrary reading of the term "requirement." While the context in which the term is used in other provisions of the MDA may arguably limit its scope to positive enactments, Section 360k(a) gives the term its broadest possible meaning by referring to "*any* requirement" established by a State. The MDA's legislative history cannot displace the unambiguous meaning of this phrase. In any event, contrary to petitioner's assertion, it is far from "unprecedented" for Congress to preempt a small class of state-law claims without providing an alternate federal remedy, where doing so is essential to achieving an important federal objective, such as promoting the public health through the establishment of a comprehensive federal regulatory framework for medical devices.

B. Petitioner's claims would impose state "requirements" that are specific to the Evergreen Balloon Catheter. As Justice Breyer recognized in his *Lohr* concurrence, there is no difference for preemption purposes between a requirement imposed on a medical device by a state regulation and one imposed by state common law.

If this case reaches trial, a jury will be required to decide whether, when applied to the Evergreen

Balloon Catheter, New York common law imposes design, manufacturing, and labeling requirements with which the device failed to comply. A verdict in petitioner's favor would therefore have the same practical effect as a New York regulation requiring Medtronic to design, manufacture, and label the Evergreen Balloon Catheter in a manner different than that approved by the FDA. These substantive, device-specific requirements—whether imposed by common law or regulation—are preempted by Section 360k(a).

III. Petitioner never argued below that her state-law claims escape the preemptive reach of Section 360k(a) because they are "parallel" to the federal requirements imposed by the PMA approval order. This Court therefore need not reach that issue. In any event, the argument is unavailing because petitioner's state-law claims rest on the premise that the Evergreen Balloon Catheter was defective under state law *despite* being designed, manufactured, and labeled in conformity with its PMA specifications. The state-law requirements that petitioner is seeking to impose are therefore directly at odds with—rather than parallel to—the Evergreen Balloon Catheter's PMA requirements.

IV. Finally, preemption of petitioner's state-law claims furthers the MDA's regulatory objectives.

A. Congress enacted the MDA to promote the public health by ensuring the widespread availability of safe and effective medical devices. Congress intended for the MDA's regulatory framework to draw a careful balance between the goals of safety and technological innovation. Preemption of state-law claims challenging the design, manufacturing, and labeling of PMA-approved devices is essential to at-

taining Congress's public-health objectives because, in the absence of preemption, medical device manufacturers would be subject to overlapping—and potentially irreconcilable—state and federal regulatory requirements. The existence of such conflicting regulatory standards would significantly complicate the task of bringing new medical devices to market. Moreover, without preemption, lay juries would be empowered to second-guess the FDA's expert regulatory judgments regarding the safety and effectiveness of PMA-approved devices. For this reason, the FDA itself supports preemption in this case.

B. The class of plaintiffs left without a common-law remedy by the Second Circuit's holding is exceedingly small. The vast majority of medical devices reach the market through the § 510(k) notification process, which does not preempt state-law claims. In addition, even PMA-approved devices are subject to breach-of-warranty and negligent manufacturing claims because those claims are not "different from" or "in addition to" the federal requirements to which a PMA-approved device must adhere.

The judgment below should be affirmed.

ARGUMENT

Federal law expressly prohibits States from "establish[ing] or continu[ing] in effect with respect to a device intended for human use any requirement which is different from, or in addition to, any requirement applicable under [the FDCA] to the device, and which relates to the safety or effectiveness of the device." 21 U.S.C. § 360k(a). As the Second Circuit held, each of the statutory prerequisites to preemption is satisfied in this case.

The Evergreen Balloon Catheter is subject to a set of federal, device-specific design, manufacturing,

and labeling "requirements" embodied in its FDA-approved PMA application. Petitioner's claims allege that New York law also establishes specific substantive standards for the Evergreen Balloon Catheter's design, manufacturing, and labeling, and that the device failed to comply with those state-law standards. These claims therefore constitute state-law "requirement[s]" "with respect to" the device that are "different from" and "in addition to" the device-specific design, manufacturing, and labeling "requirements applicable under [the FDCA]." Finally, these state-law requirements relate to the "safety or effectiveness" of the Evergreen Balloon Catheter because they rest on the allegation that—when designed, manufactured, and labeled in accordance with its PMA specifications—the device was unsafe and did not effectively perform its intended function when used to treat Mr. Riegel.

Because petitioner is directly challenging the FDA's expert judgment that the Evergreen Balloon Catheter is safe and effective, her claims are foreclosed by Section 360k(a).

I. THE PMA PROCESS IMPOSES DEVICE-SPECIFIC FEDERAL "REQUIREMENTS" ON THE EVERGREEN BALLOON CATHETER.

The Second Circuit held that a medical device that has obtained PMA approval is "subject to the federal, device-specific requirement of adhering to the standards contained in its individual, federally approved PMA," and that these requirements therefore have preemptive force under Section 360k(a). Pet. App. 26a. This conclusion is consistent with this Court's description of the "rigorous," device-specific FDA inquiry that every PMA device must undergo—an inquiry that this Court repeatedly distinguished

from the "limited" and "by no means comparable" § 510(k) notification process. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 478 (1996).

A. Unlike § 510(k) Review, The PMA Process Establishes Device-Specific Federal "Requirements."

The PMA process involves an "exhaustive" and "time-consuming" review of a medical device's design, manufacturing, and labeling. *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 344, 349 (2001). The FDA spends hundreds of hours during the PMA process reviewing clinical and nonclinical studies to determine whether a particular device would be safe and effective when designed, manufactured, and labeled in conformity with the specifications set forth in the voluminous PMA application. *See Lohr*, 518 U.S. at 477. On the basis of this information, the FDA "weigh[s] any probable benefit to health from the use of the device against any probable risk of injury or illness from such use." 21 U.S.C. § 360c(a)(2)(C).

PMA approval signals that the FDA has found the device to be safe and effective when designed, manufactured, and labeled in conformity with the specifications of the PMA application. FDA, Premarket Approval 1. Accordingly, upon receiving approval, the manufacturer may market the device *only* as specified in the PMA application approved by the FDA. Any change to the device's design, manufacturing, or labeling that affects its safety or effectiveness must be approved by the FDA before the modified device may be marketed. 21 U.S.C. § 360e(d)(6)(A)(i); J.A. 21. The FDA's approval of a PMA application therefore establishes a set of device-specific design, manufacturing, and labeling re-

quirements to which the manufacturer must adhere. *Cf.* 21 U.S.C. § 360j(a) (referring to "requirement[s] imposed on [a] device under section . . . 360e," which governs the PMA process); *id.* § 382(a)(2)(A) (same).

These device-specific requirements embody the substantive judgment of the FDA regarding a device's safety and effectiveness, and distinguish the PMA process from the streamlined § 510(k) notification process considered in *Lohr*. In contrast with the PMA process—which is "specifically focused on safety and requires a significant weighing of considerations specific to the device before approval is granted" (*Martin v. Medtronic, Inc.*, 254 F.3d 573, 584 (5th Cir. 2001))—"the § 510(k) process lacks the PMA review's rigor" and "requires only a showing of substantial equivalence to a predicate device." *Buckman*, 531 U.S. at 348. The pacemaker lead at issue in *Lohr* thus had never been reviewed by the FDA for safety and effectiveness because it reached the market through the § 510(k) notification process. In authorizing the manufacturer to market the product, the FDA had merely concluded that the pacemaker lead was "substantially similar" to a device that had been marketed before the enactment of the MDA. Indeed, when communicating to the manufacturer that the device had cleared the § 510(k) notification process, the FDA "emphasized . . . that this determination should not be construed as an endorsement of the pacemaker lead's safety." *Lohr*, 518 U.S. at 480. Although the pacemaker lead was subject to manufacturing and labeling requirements applicable to all medical devices, this Court explained that they did not have preemptive effect because they "reflect[ed] important but entirely generic concerns about device regulation generally, not the sort of concerns regarding a specific device or field of device regulation that

the [MDA] statute or regulations were designed to protect from potentially contradictory state requirements." *Id.* at 501.

PMA-approved devices, in contrast, are subject to a set of requirements that embody precisely "the sort of concerns regarding a specific device" that Congress intended to insulate from different or additional state-law requirements. FDA approval of a PMA application reflects the agency's device-specific determination that the product is safe and effective and therefore appropriate for marketing in conformity with the design, manufacturing, and labeling specifications approved by the FDA. The MDA shields these expert agency determinations from conflicting state-law evaluations of safety and effectiveness. *See Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 871 (2000) (preemption of state-law safety standards is necessary "to avoid the conflict, uncertainty, cost, and occasional risk to safety itself that too many different safety-standard cooks might otherwise create").[3]

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[3] Contrary to the contention of *amicus curiae* AARP that the PMA process is merely a "one-time licensing scheme" (Br. of AARP et al. 14), the FDA's stringent oversight of the safety and effectiveness of PMA-approved devices does not end when an approval order is issued. A manufacturer of a PMA-approved device is required to submit an annual report to the FDA summarizing additional clinical and nonclinical studies regarding the device (21 C.F.R. § 814.84(b)), and to inform the FDA within ten days of learning that a device has caused an adverse reaction in a patient. J.A. 23. The FDA also undertakes periodic inspections of the facilities at which PMA-approved devices are manufactured in order to ensure that they are being produced in compliance with the manufacturing methods specified in the PMA application and approved by the FDA. 21 U.S.C. § 360(h); FDA, Premarket Approval 34. Where the FDA determines that a PMA-approved device presents an unreasonable risk of sub-

B. The Preemptive Effect Of PMA Approval Is Consistent With *Lohr* And The FDA's Regulatory Framework.

Petitioner advances five contrary arguments in an effort to obscure the existence of these preemptive, device-specific federal requirements. Each of petitioner's arguments is unavailing.

First, petitioner is wrong to contend that Medtronic is relying upon the same federal requirements that were considered in *Lohr* as the basis for preemption. Pet. Br. 30. Petitioner argues, for example, that the federal labeling requirements at issue in this case are no different than those in *Lohr*. *Id.* But while the pacemaker lead in *Lohr* was only subject to the FDA's general labeling requirements (*see, e.g.*, 21 C.F.R. § 801.109)—which this Court found to be insufficiently device-specific to trigger preemption (518 U.S. at 501)—the FDA substantively reviewed the proposed labeling for the Evergreen Balloon Catheter set forth in its PMA application, approved that labeling as adequate to ensure safety and effec-

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[Footnote continued from previous page]

stantial harm to the public, it can order the manufacturer to repair, replace, or cease distribution of the device, or can order a recall of the device. 21 U.S.C. § 360h. Petitioner nevertheless contends that the FDA's postmarket surveillance is somehow deficient because the FDA is not frequently required to issue a recall order to secure the removal of a dangerous device from the market but has generally been able to rely on manufacturers' voluntary compliance with its recall requests. *See* Pet. Br. 6 & n.2. Conduct taken under the threat of government action, however, is just as much the product of government regulation as conduct that the government has explicitly directed a person to undertake. *See, e.g., MedImmune, Inc. v. Genentech, Inc.*, 127 S. Ct. 764, 772-73 (2007).

tiveness, and precluded Medtronic from making changes without further FDA approval. The Evergreen Balloon Catheter thus must adhere to these device-specific labeling requirements, not simply to the general labeling requirements that this Court considered in *Lohr*. *See Lohr*, 518 U.S. at 501 (distinguishing the "generality of those requirements" applicable to a § 510(k)-cleared device from "a case in which the Federal Government has weighed the competing interests relevant to the particular requirement in question, reached an unambiguous conclusion about how those competing considerations should be resolved in a particular case or set of cases, and implemented that conclusion via a specific mandate on manufacturers").[4]

Second, petitioner argues that—notwithstanding the device-specific design, manufacturing, and labeling requirements established by PMA approval of the Evergreen Balloon Catheter—the MDA's preemption

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[4] Petitioner attempts to evade the MDA's preemptive reach by arguing that Medtronic could have issued a "Dear Doctor" letter informing physicians of the purported defects in the Evergreen Balloon Catheter. Pet. Br. 31. Petitioner did not raise that argument below, and this Court therefore need not reach it. *See United States v. United Foods, Inc.*, 533 U.S. 405, 416-17 (2001). In any event, petitioner's argument is without merit because FDA regulations define the scope of Medtronic's obligation to inform doctors about potential device defects in PMA-approved devices. *See* 21 U.S.C. § 360h(a). The mere fact that federal law *allows* a manufacturer to send a "Dear Doctor" letter does not mean that federal law *requires* a manufacturer to do so. Were state-law tort liability premised on Medtronic's failure to do something that is permitted but not required under federal law, state law would clearly be imposing a preempted requirement "different from, or in addition to," the federal requirements applicable to the Evergreen Balloon Catheter.

provision should be confined to federal requirements established by an FDA-promulgated regulation. Pet. Br. 27-28. But this artificially narrow reading of Section 360k(a) collapses under scrutiny.

Petitioner effectively concedes that the FDA could preempt different or additional state-law requirements regarding the design, manufacturing, or labeling of the Evergreen Balloon Catheter by promulgating a set of regulations that embodied the FDA's expert regulatory judgment regarding those features of the device. *See* Pet. Br. 27 ("If the FDA issued a standard requiring PTCA catheters to meet certain specifications, a design-defect claim that challenged the safety of the device could be analyzed in terms of whether design requirements implied by the claim (if any) were different from or in addition to those specifications.") (internal quotation marks and citation omitted). Petitioner nevertheless insists that the FDA's approval of Medtronic's PMA application—which signals that, in the FDA's expert regulatory judgment, the device is safe and effective when designed, manufactured, and labeled in conformity with the PMA application's specifications—does not have preemptive effect.

Both petitioner's hypothetical set of regulations and the PMA approval order, however, embody the same expert regulatory determination regarding the Evergreen Balloon Catheter's safety and effectiveness; there is simply no principled basis—and certainly no basis in the language of Section 360k(a)—for affording that device-specific regulatory judgment preemptive effect only when embodied in a regulation. *Cf. Sprietsma v. Mercury Marine*, 537 U.S. 51, 64 (2002) (recognizing that even an agency's decision not to engage in regulation can have preemptive effect). Indeed, the FDA regulation on which peti-

tioner relies to substantiate her insistence on the promulgation of an agency regulation as a prerequisite to preemption provides that "[s]tate or local requirements are preempted only when the [FDA] has established specific counterpart regulations or there are *other specific requirements* applicable to a particular device under the" MDA. 21 C.F.R. § 808.1(d) (emphasis added). The phrase "other specific requirements" must refer to something other than the "specific counterpart regulations" also mentioned in Section 808.1(d). In this case, those "other specific requirements applicable to a particular device" are the device-specific design, manufacturing, and labeling specifications that the FDA established—and from which the Evergreen Balloon Catheter may not deviate—when it approved Medtronic's PMA application.

Third, petitioner asserts that the FDA does not itself develop the design, manufacturing, or labeling for a PMA-approved device and that this precludes the PMA process from establishing device-specific requirements. Pet. Br. 24. Petitioner is wrong to suggest that the FDA never develops a device's design, manufacturing, or labeling specifications. The FDA can direct a manufacturer to alter its proposed specifications for a device as a condition of receiving PMA approval, and there is often substantial back-and-forth between the FDA and the manufacturer during the PMA process. 21 C.F.R. § 814.44(e). In any event, it is completely irrelevant to the preemption inquiry whether the FDA avails itself of its authority to direct modification of a product's design, manufacturing, and labeling or whether it concludes that the device is safe and effective when marketed in accordance with the specifications developed by the manufacturer. Petitioner cites nothing in the

MDA to support such a distinction. Whether the design, manufacturing, and labeling specifications approved by the FDA were proposed by the FDA itself or by the manufacturer, the PMA approval order establishes a set of device-specific requirements from which the manufacturer may not deviate and that preempt counterpart state requirements. Indeed, it would be ironic, to say the least, if the MDA afforded less preemption protection to the manufacturer of a device that the FDA found to be safe and effective based on the specifications in its initial PMA application than to a manufacturer that was required by the FDA to make design, manufacturing, or labeling changes in order to obtain PMA approval.[5]

Fourth, the generality of the approval letter notifying Medtronic that its PMA application for the Evergreen Balloon Catheter had been approved is also irrelevant to the preemption inquiry. Pet. Br. 28-29. It is not the approval letter or the Conditions of Ap-

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[5] Petitioner is wrong to rely upon *American Airlines, Inc. v. Wolens*, 513 U.S. 219 (1995), to suggest that the MDA does not preempt her claims because it "does not require a manufacturer to market any product." Pet. Br. 27. *Wolens* simply concluded that the Airline Deregulation Act, which prohibited States from "enacting or enforcing any law . . . relating to [air carrier] rates, routes, or service," 49 U.S.C. App. § 1305(a)(1) (1988 ed. & Supp. V), did not preempt state-law breach-of-contract actions against an airline because these contractual obligations were self-imposed by the airline, rather than imposed by the State, and the airline could have unilaterally revised its obligations without obtaining regulatory approval. *Wolens*, 513 U.S. at 228-29. In contrast, the design, manufacturing, and labeling requirements to which a PMA-approved device must adhere are imposed by the FDA through its approval of a PMA application, and the manufacturer may not deviate from these requirements without obtaining further FDA approval. 21 U.S.C. § 360e(d)(6)(A)(i).

proval attached to that letter that establishes the specific design, manufacturing, and labeling requirements to which a device is subject. It is the PMA application, as reviewed and approved by the FDA, that sets forth these specifications.

Finally, the fact that the Court held that § 510(k) clearance does not have preemptive effect—even though a manufacturer of a § 510(k)-cleared device may not make changes to that device without obtaining additional FDA approval—has no bearing on whether PMA approval has preemptive force. Clearance under the § 510(k) notification process merely reflects the FDA's conclusion that a device is substantially similar to a device marketed before the enactment of the MDA; it does not embody the FDA's expert regulatory judgment regarding the safety and effectiveness of the product. *See Lohr*, 518 U.S. at 493 (the "510(k) process is focused on *equivalence*, not safety") (internal quotation marks omitted). Thus, under the § 510(k) notification process, the FDA does "not 'require' [a device] . . . to take any particular form for any particular reason." *Id.* at 493. In contrast, when the FDA approves a PMA device, it prohibits modifications to the device's design, manufacturing, and labeling for the very "particular reason" that it has concluded that the device is safe and effective when designed, manufactured, and labeled in accordance with its FDA-approved specifications. The FDA prohibits deviations from those strict specifications because they could compromise the device's safety and effectiveness and imperil the public health.

II. PETITIONER'S COMMON-LAW CLAIMS SEEK TO IMPOSE STATE-LAW "REQUIREMENTS" "WITH RESPECT TO" THE EVERGREEN BALLOON CATHETER.

The Second Circuit held that, "if successful," petitioner's state-law products liability claims would impose state-law "requirements" regarding the design, manufacturing, and labeling of Medtronic's Evergreen Balloon Catheter. Pet. App. 32a. This conclusion is supported by *Lohr*'s holding that state common-law claims constitute "requirements" under Section 360k(a) and by the fact that petitioner's claims seek to establish a set of "substantive" obligations that are specific to the design, manufacturing, and labeling of the Evergreen Balloon Catheter. *Lohr*, 518 U.S. at 500.

A. Common-Law Claims Constitute "Requirements" Under Section 360k(a).

Disregarding the clear holding of a majority of the Court in *Lohr*, petitioner contends that state common-law claims can *never* constitute "requirements" under the MDA. Petitioner's argument is at odds with this Court's precedent and the plain language of Section 360k(a).

1. A majority of this Court held in *Lohr* that state common-law claims constitute "requirements" under Section 360k(a). *See* 518 U.S. at 509 (O'Connor, J., concurring in part and dissenting in part, joined by Chief Justice Rehnquist, and Justices Scalia and Thomas) ("state common-law damages actions do impose 'requirements'"); *id.* at 503, 504 (Breyer, J., concurring in part and concurring in the judgment) (expressly "agree[ing]" with Justice O'Connor's "conclusion" that the MDA preempts cer-

tain state-law tort actions). Petitioner concedes this point in discussing *Lohr*. *See* Pet. Br. 9 ("Justice Breyer filed a concurring opinion stating that, in his view, § 360k(a)'s reference to state-law 'requirements' encompasses some state-law damages claims."); *id.* at 10 ("In [Justice O'Connor's] view, state-law damages claims could constitute 'requirements' under § 360k(a)."). Petitioner nevertheless devotes more than eight pages of her brief (at 14-23) to arguing that state common-law claims are not "requirements" under the MDA—without once acknowledging that she is asking this Court to overrule a holding reached by a majority of the Court in *Lohr*.

Petitioner's argument is squarely foreclosed by this Court's precedent, and there is no reason for the Court to revisit this aspect of *Lohr* here. Indeed, this Court has long recognized that damages awards are an effective means of securing regulatory compliance. *See San Diego Bldg. Trades Council v. Garmon*, 359 U.S. 236, 247 (1959) ("[State] regulation can be as effectively exerted through an award of damages as through some form of preventive relief. The obligation to pay compensation can be, indeed is designed to be, a potent method of governing conduct and controlling policy."). The Court's holding in *Lohr* that state common-law claims can constitute state-law "requirements" under the MDA is consistent with both this well-established principle and with pre-*Lohr* and post-*Lohr* precedent. *See, e.g.*, *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 521 (1992) (plurality op.) ("The phrase '[n]o requirement or prohibition' sweeps broadly and suggests no distinction between positive enactments and common law; to the contrary, those words easily encompass obligations that take the form of common-law rules."); *see also id.* at 548-49 (Scalia, J., concurring in the judgment in part and

dissenting in part) (same). *Lohr*'s holding on this point was recently reaffirmed in *Bates v. Dow Agrosciences LLC*, 544 U.S. 431 (2005), where the Court held that the term "requirement" in the preemption provision of the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA") "reaches beyond positive enactments, such as statutes and regulations, to embrace common-law duties." *Id.* at 443.[6]

Any conceivable doubt on this point is dispelled by the regulations that the FDA has promulgated pursuant to the MDA, which explicitly contemplate the preemption of state common-law claims. *See* 21 C.F.R. § 808.1(b) (Section 360k(a) "prescribes a general rule that . . . no State or political subdivision of a State may establish or continue in effect any re-

[6] Petitioner cites this Court's statement in *Bates* that an "event, such as a jury verdict, that merely motivates an optional decision is not a requirement" for preemption purposes. 544 U.S. at 445; *see also* Pet. Br. 12, 39. That statement does not detract from the force of this Court's unambiguous holding in *Bates* that state common-law claims can constitute "requirements." The statement relied upon by petitioner merely rejected the court of appeals' reasoning that a jury verdict that induces a pesticide manufacturer to make the optional decision to alter the labeling or packaging of its product could constitute a "requirement[ ] for labeling or packaging" within the meaning of FIFRA, even if the underlying state-law claim did not actually pertain to the product's labeling or packaging. The Court explained that a requirement "is a rule of law that must be obeyed," rather than an inducement to make an optional decision. *Bates*, 544 U.S. at 445. Here, petitioner's state-law products liability claims, if successful, would impose rules of law that pertain directly to the safety and effectiveness of the Evergreen Balloon Catheter. Indeed, accepting petitioner's reading of this aspect of *Bates* would require this Court to disavow its holdings in both *Bates* and *Cipollone* that state common-law claims—and the jury verdicts to which they may give rise—are "requirements" for preemption purposes.

quirement with respect to a medical device intended for human use having the force and effect of law (whether established by statute, ordinance, regulation, or *court decision*) . . . .") (emphasis added).

2. Because a majority of this Court has already authoritatively determined that state common-law claims constitute "requirements" under Section 360k(a), this Court need not consider each of petitioner's arguments on this point. *Stare decisis* is sufficient to dispose of all of them. In any event, none of petitioner's three arguments has merit.

Petitioner first contends that the plain language of Section 360k(a) supports the exclusion of common-law claims from the scope of the term "requirement" because the MDA's other references to the term are purportedly limited to positive enactments. The term's other iterations shed no light, however, on whether a state common-law action constitutes a "requirement" under Section 360k(a). Even if petitioner is correct that, as used elsewhere in the MDA, the term is effectively limited to positive enactments, it is the context in which the term is used in these other instances—rather than the definition of the term "requirement" itself—that performs this limiting function.

Section 360k(a), for example, defines preemptive federal "requirements" as "any requirement applicable under this chapter to the device." 21 U.S.C. § 360k(a)(1); *see also id.* § 360k(a)(2) (referring to "a requirement applicable to the device under this chapter"). It is the modifier "applicable under this chapter" that limits preemptive federal requirements to positive enactments, not the definition of the term "requirement." When describing the state laws that Section 360k(a) preempts, however, Congress did not

utilize any limiting modifier at all, but instead gave the term "requirement" its broadest possible reach by extending Section 360k(a) to "*any* requirement." 21 U.S.C. § 360k(a)(1) (emphasis added); *cf.* 5 U.S.C. § 504(a)(4) (referring to "compliance with a statutory or regulatory requirement").

For this same reason, the fact that States may not be able to secure exemptions for state common-law claims under Section 360k(b) merely reflects the fact that it may be exceedingly difficult to demonstrate that a state common-law claim is "more stringent" than a federal requirement or is "required by compelling local conditions." 21 U.S.C. § 360k(b). Although it may not be possible to obtain an exemption for some types of "requirements" under Section 360k(b) due to the exacting prerequisites to securing an exemption, this does not even remotely suggest that the expansive phrase "any requirement" as used in Section 360k(a) does not itself include common-law claims.[7]

Petitioner's reliance on Section 360h(d) of the MDA is similarly misplaced. While Section 360h(d) makes clear that compliance with a repair, replacement, or refund order issued under that section does not "relieve any person from liability under . . . State law," that savings clause does not support petitioner's far-reaching assertion that *all* state common-law claims are outside the scope of the MDA's preemption provision. Section 360h(d) merely suggests that *some* state common-law claims survived the enactment of the MDA—a result fully consistent with the Second

[7] It is therefore irrelevant whether the FDA regulation governing the procedure for obtaining an exemption limits the availability of exemptions to positive enactments. *See* 21 C.F.R. § 808.1(d); Pet. Br. 32.

Circuit's holding that Section 360k(a) preempts state common-law claims that would impose different or additional state-law requirements on PMA-approved devices, but not those "tort claims that are premised on a manufacturer's deviation from the standards set forth in the device's approved PMA application." Pet. App. 36a. *Lohr*'s holding that the MDA does not expressly preempt state-law claims regarding devices that have undergone the § 510(k) notification process creates a further universe of state-law claims that survived the MDA's enactment. The MDA's preemption of state common-law claims that would impose different or additional requirements on PMA-approved devices therefore leaves numerous state-law claims to be "saved" by Section 360h(d).

Finally, petitioner relies on Congress's failure to discuss the preemption issue in the MDA's legislative history as evidence that the statute was not intended to preempt any state common-law claims. But this Court has often warned of the dangers of relying on congressional silence where a statute's meaning is clear from its plain language. *See Whitfield v. United States*, 543 U.S. 209, 216 (2005); *see also Harrison v. PPG Indus., Inc.*, 446 U.S. 578, 592 (1980) ("it would be a strange canon of statutory construction that would require Congress to state in committee reports or elsewhere in its deliberations that which is obvious on the face of a statute"). This Court has recognized that the term "requirement" "easily encompass[es] obligations that take the form of common-law rules." *Cipollone*, 505 U.S. at 521 (plurality op.). As in *Cipollone* and *Bates*—where the Court concluded that Congress intended to preempt state common-law claims without resorting to legislative history—this unambiguous language (rather than ambiguous congres-

sional silence on the topic) should determine the preemptive reach of Section 360k(a).[8]

Indeed, petitioner places far too much weight on the circumstances surrounding Congress's enactment of the MDA. Petitioner asserts, for example, that "for Congress to have preempted damages claims without providing an alternative means of compensation would have been unprecedented." Pet. Br. 18. But that is simply not so. Seven years before the MDA's enactment, Congress amended the Federal Cigarette Labeling and Advertising Act to preempt state-law cigarette advertising "requirement[s] . . . based on smoking and health." 15 U.S.C. § 1334(b). Although Congress did not provide an alternate federal remedy in the statute, this Court held in *Cipollone* that the Labeling Act preempts certain state-law claims against tobacco companies. 505 U.S. at 524, 527 (plurality op.); *see also Pilot Life Ins. Co. v. Dedeaux*, 481 U.S. 41, 55 (1987) (holding that a state-law claim was preempted by the Employee Retirement Income Secu-

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[8] Congress's use of the unambiguous term "requirement" to define the scope of preemption under the MDA also forecloses petitioner's reliance upon the presumption against preemption. Pet. Br. 21-22. As *Cipollone* and *Bates* establish, that general presumption cannot nullify Congress's intention to displace state common-law claims by enacting statutes that preempt state "requirements."

Moreover, the fact that this Court had not yet definitively held that the term "requirement" encompasses state common-law claims when Congress enacted the MDA in 1976 has no more relevance than the presumption against preemption. Pet. Br. 22. The statutes at issue in *Cipollone* and *Bates* were also enacted before this Court had reached such a conclusion. That fact did not carry any weight, however, when the Court construed the term "requirement" in *Cipollone* and *Bates* to reach state common-law claims.

rity Act, even though "the state action purported to authorize a remedy unavailable under the federal provision").

Thus, contrary to petitioner's assertion, it certainly was not "unprecedented" for Congress, at the time it enacted the MDA, to preempt state common-law actions without providing an alternate federal remedy. Moreover, petitioner fails to acknowledge that the class of plaintiffs who are left without any viable cause of action by the preemptive force of Section 360k(a) is exceedingly small because the MDA does not preempt state-law claims regarding § 510(k)-cleared devices or state-law claims alleging that a PMA-approved device failed to comply with a design, manufacturing, or labeling requirement established by the PMA process. As discussed below, Congress made the reasoned determination that preemption of the small category of claims challenging the FDA-approved design, marketing, and labeling of PMA devices would promote the public health by encouraging the development of new life-saving medical technologies. *See infra* Part IV.[9]

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[9] Petitioner also attempts to rely upon the fact that the first PMA preemption cases were not decided until more than a decade after the MDA was enacted to suggest that not even device manufacturers themselves, at the time of the MDA's enactment, considered the possibility that the statute preempted state common-law claims regarding PMA-approved devices. Pet. Br. 22 n.6. But that delay is merely a product of the time that it typically takes to bring a new PMA-approved device to market and the fact that there is generally at least several years between the introduction of a new PMA-approved device and a court decision in a products liability action concerning that device.

B. Petitioner's Common-Law Claims Would Impose "Requirements" That Are Specific To The Evergreen Balloon Catheter.

Petitioner contends that, even if state common-law claims can constitute "requirements" under Section 360k(a), her claims are not preempted because "the principles of New York law on which [they] rely . . . are principles of 'general applicability' outside the scope of § 360k(a)." Pet. Br. 34-35 (quoting *Lohr*, 518 U.S. at 500) (citations omitted). But an examination of this Court's opinion in *Lohr* and the New York common-law requirements that petitioner is attempting to impose upon the Evergreen Balloon Catheter conclusively establishes that petitioner's causes of action satisfy *Lohr*'s specificity requirement.[10]

1. Section 360k(a) provides that state-law requirements "with respect to a device" are preempted.

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[10] As an initial matter, the plain language of Section 360k(a) does not refer to "specific" state-law requirements, but instead encompasses "any requirement which is different from, or in addition to," a federal MDA requirement. 21 U.S.C. § 360k(a). As Justice O'Connor observed in *Lohr*, "The statute makes no mention of a requirement of specificity, and there is no sound basis for determining that such a restriction on 'any requirement' exists." 518 U.S. at 512 (O'Connor, J., concurring in part and dissenting in part). Thus, to the extent that this Court concludes that petitioner's common-law claims do not satisfy *Lohr*'s specificity requirement, it should reconsider this aspect of *Lohr* and hold—consistent with the plain statutory language—that Section 360k(a) "pre-empts any state common-law action that would impose a requirement different from, or in addition to, that applicable under the FDCA." *Id.* at 511. Petitioner's common-law claims are preempted under that standard because, if successful, they would impose requirements on the Evergreen Balloon Catheter that are different from those established by the FDA through its PMA approval order.

21 U.S.C. § 360k(a). In *Lohr*, this Court concluded that the "general state common-law requirements" that the plaintiffs were attempting to impose upon the defendant's pacemaker "were not specifically developed 'with respect to' medical devices" and therefore were not preempted. 518 U.S. at 501. Although a plurality of the Court thought it "apparent that few, if any, common-law duties have been preempted by" the MDA because "[i]t will be rare indeed for a court hearing a common-law cause of action to issue a decree that has 'the effect of establishing a substantive requirement for a specific device'" (*id.* at 502-03 (quoting 21 C.F.R. § 808.1(d)(6)(ii))), a *majority* of the Court explicitly rejected the notion that state common-law claims would only "rare[ly]" satisfy the specificity requirement. *See id.* at 508 (Breyer, J., concurring in part and concurring in the judgment) ("I am not convinced that future incidents of MDA pre-emption of common-law claims will be 'few' or 'rare.'") (citation omitted); *id.* at 509 (O'Connor, J., concurring in part and dissenting in part) (labeling the plurality's assertion that MDA preemption will be "rare" "bewildering and seemingly without guiding principle").

In his concurrence, Justice Breyer elaborated upon the circumstances in which a state common-law claim would be sufficiently specific to the medical device setting to give rise to preemption under Section 360k(a). He posited a situation where "a federal MDA regulation requires a 2-inch wire, but a state agency regulation requires a 1-inch wire" for a hearing-aid component. *Lohr*, 518 U.S. at 504 (Breyer, J., concurring in part and concurring in the judgment). "If the federal law, embodied in the '2-inch' MDA regulation, pre-empts the state '1-inch' agency regulation," Justice Breyer asked, "why would it not simi-

larly pre-empt a state-law tort action that premises liability upon the defendant manufacturer's failure to use a 1-inch wire (say, an award by a jury persuaded by expert testimony that use of a more than 1-inch wire is negligent)?" *Id.* Justice Breyer recognized that the "effects of the state agency regulation and the state tort suit are identical" and that "[t]o distinguish between them for pre-emption purposes would grant greater power (to set state standards 'different from, or in addition to,' federal standards) to a single state jury than to state officials acting through state administrative or legislative lawmaking processes." *Id.*

Petitioner is asking this Court to draw the exact "distin[ction]" that Justice Breyer—and four other Justices—rejected in *Lohr*. Petitioner is alleging that Medtronic was negligent and is strictly liable under New York law because it designed, manufactured, and labeled the Evergreen Balloon Catheter in conformity with the FDA-approved specifications set forth in its PMA application. If this case reaches trial, petitioner will argue that New York common law required that Medtronic design and manufacture the Evergreen Balloon Catheter in a manner different than that specified in its FDA-approved PMA application and that these alternative design and manufacturing techniques would have prevented the device from rupturing when used during Mr. Riegel's angioplasty. *See* Pet. Br. 11 ("The design-defect claim alleges that the product was not designed adequately to function as intended . . . ."). Petitioner will further argue that New York common law required Medtronic to include a more explicit warning about the risk of rupture and/or more specific instructions for use on the Evergreen Balloon Catheter's label than the warning and instructions ap-

proved by the FDA. *See id.* ("The inadequate warning claim focuses on conflicting information on the label . . . .").

It is the application of these general common-law duties to a specific PMA-approved device that triggers the preemptive effect of Section 360k(a). Indeed, this Court has recognized that "[s]tate power may be exercised as much by a jury's application of a state rule of law in a civil lawsuit as by a statute" or regulation. *BMW of N. Am., Inc. v. Gore*, 517 U.S. 559, 572 n.17 (1996). Thus, "while [a] general [common-law] duty, standing on its own, is not a threat to federal requirements and is not developed specifically 'with respect to' medical devices, the elements needed to prove a violation of that general duty may be very specifically tailored to the device, and the state court action may therefore threaten specific federal requirements." *Martin*, 254 F.3d at 582.

If a jury finds in petitioner's favor in this case, that verdict will be based on the conclusion that New York common-law imposes design, manufacturing, and labeling requirements for the Evergreen Balloon Catheter that are different than those established by the FDA during the PMA process. Those state common-law requirements are just as assuredly "establish[ed] . . . with respect to a device," and are just as assuredly "different from, or in addition to," the requirements established by the FDA, as a set of New York regulations explicitly imposing design, manufacturing, and labeling requirements on balloon catheters. Indeed, whether New York promulgates a regulation requiring balloon catheters to have a rated burst pressure higher than that of the Evergreen Balloon Catheter or a jury finds Medtronic liable under New York common law because it concludes that the Evergreen Balloon Catheter should

have been designed with a higher rated burst pressure, the result would be the same: New York state law would require Medtronic to design, manufacture, and label its device in a manner that diverged from the FDA-approved specifications in its PMA application. *See Cipollone*, 505 U.S. at 521 (plurality op.) ("The obligation to pay compensation can be, indeed is designed to be, a potent method of governing conduct and controlling policy") (quoting *San Diego Bldg. Trade Council*, 359 U.S. at 247).

Petitioner's common-law claims, if successful, would therefore "have 'the effect of establishing a substantive requirement for a specific device'" (*Lohr*, 518 U.S. at 500), and are preempted by Section 360k(a).

2. The FDA regulations on which petitioner relies do not support a different conclusion. Petitioner invokes 21 C.F.R. § 808.1(d)(1), which provides that Section 360k(a) does not preempt state requirements "of general applicability where the purpose of the requirement relates either to other products in addition to devices (e.g., requirements such as general electrical codes, and the Uniform Commercial Code (warranty of fitness)), or to unfair trade practices in which the requirements are not limited to devices." 21 C.F.R. § 808.1(d)(1). This regulation does not—as petitioner contends—limit the preemptive reach of Section 360k(a) to statutory and regulatory requirements that apply specifically and exclusively to medical devices or to common-law causes of action that are applicable only in the device context. Indeed, because there are unlikely to be *any* state common-law causes of action that apply only to medical devices, that reading would essentially nullify the MDA's preemptive effect on state common-law claims—in direct contravention of Congress's inten-

tion to extend Section 360k(a) to "*any* requirement" imposed under state law. *See Lohr*, 518 U.S. at 508 (Breyer, J., concurring in part and concurring in the judgment) ("future incidents of MDA pre-emption of common-law claims will [not] be 'few' or 'rare'") (citation omitted); *cf. Watters v. Wachovia Bank, N.A.*, 127 S. Ct. 1559, 1572 & n.13 (2007) (where a federal statute preempts state law, federal regulations have no bearing on the preemption inquiry).

As the FDA explained at the time it promulgated Section 808.1(d)(1), the regulation was intended to clarify that Section 360k(a) does not preempt state requirements "of general applicability that relate only *incidentally* to medical devices." 42 Fed. Reg. 30,383, 30,384 (June 14, 1977) (emphasis added). A state common-law negligence or strict liability action challenging the design, manufacturing, and labeling of a device is far from only "incidentally" related to that device. If state-law liability is imposed in such a suit, it will be based on a finding that the state common law included a substantive requirement that the device be designed, manufactured, or labeled in a manner different than that approved by the FDA. Unlike requirements that a device comply with the general warranty of fitness—which imposes the same obligation on manufacturers of all products—the parameters of these common-law design, manufacturing, and labeling requirements vary from device to device. A more complex device, for example, may require more extensive labeling than a comparatively more simple device in order to comply with state duty-to-warn standards. Petitioner is therefore seeking to impose a set of common-law requirements on the Evergreen Balloon Catheter that are specific not merely to the medical device context but also to the Evergreen Balloon Catheter itself.

III. THE STATE-LAW "REQUIREMENTS" THAT PETITIONER SEEKS TO IMPOSE ARE "DIFFERENT FROM" AND "IN ADDITION TO" THE FEDERAL PMA "REQUIREMENTS."

Petitioner's common-law claims allege that the Evergreen Balloon Catheter is defective—even though it was produced in accordance with its FDA-approved design, manufacturing, and labeling specifications. If successful, those claims would therefore impose state-law requirements "with respect to" the Evergreen Balloon Catheter that are "different from," and "in addition to," the federal design, labeling, and manufacturing requirements established through the PMA approval order.

In a final attempt to evade the preemptive reach of Section 360k(a), petitioner nevertheless argues—for the first time in this litigation—that her state-law claims "are based on duties that mirror federal design and labeling requirements" and therefore are not preempted. Pet. Br. 39. Petitioner never argued below that her claims would impose state-law requirements that are equivalent to the federal requirements to which the Evergreen Balloon Catheter must adhere, and this Court therefore need not reach this issue. *See United States v. United Foods, Inc.*, 533 U.S. 405, 416-17 (2001). Indeed, it would be unusual for this Court to delve into the substantive content of New York common law without the benefit of lower-court consideration.[11]

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[11] The only claim that petitioner described below as equivalent to the Evergreen Balloon Catheter's federal requirements was the negligent manufacturing claim—which was dismissed on grounds other than preemption and is not before this Court. Pet. App. 90a.

In any event, petitioner's argument that her state-law claims seek to impose requirements that are parallel to—rather than "different from, or in addition to"—the federal PMA requirements is substantially wide of the mark. In *Lohr*, this Court held that a plaintiff's allegations are not preempted to the extent they "include claims that [the device manufacturer] . . . violated FDA regulations" because those state-law requirements would be "parallel" to the federal requirements. 518 U.S. at 495. In *Bates*, this Court elaborated that a state requirement is parallel to a federal requirement only where the two are "*genuinely* equivalent"—that is, where the defendant is being held liable under state law for conduct that is also prohibited under federal law. 544 U.S. at 454. Other than the no-longer-at-issue negligent manufacturing claim, petitioner has never contended that Medtronic should be held liable under state law because the Evergreen Balloon Catheter did not comply with the federal requirements imposed by the PMA approval order. Petitioner's state-law claims are instead premised on the argument that the device—even when designed, manufactured, and labeled in the manner found to be safe and effective by the FDA—is defective. Far from being "parallel," the state-law requirements that petitioner is seeking to impose are in fact directly at odds with the federal requirements established by the FDA.

Moreover, petitioner is wrong to assert that her state-law failure-to-warn claim is parallel to the MDA's misbranding prohibition. 21 U.S.C. § 352. A plaintiff is barred from pursuing a state-law failure-to-warn claim regarding a device that is labeled in conformity with the requirements of its PMA approval order because such a claim would impermissibly seek to impose state-law labeling requirements

that would be "different from, or in addition to," the federal requirements established by the FDA. The FDA regulations unambiguously confirm that such state-law claims are foreclosed by Section 360k(a). *See* 21 C.F.R. § 808.1(d)(6)(ii) ("Where . . . a prohibition [regarding the manufacture of adulterated or misbranded devices] has the effect of establishing a substantive requirement for a specific device, e.g., a specific labeling requirement, then the prohibition will be preempted if the requirement is different from, or in addition to, a Federal requirement established under the act.").

* * *

Petitioner does not dispute that Medtronic marketed the Evergreen Balloon Catheter in conformity with the specific design, manufacturing, and labeling requirements established by the FDA in its PMA approval order. Because petitioner's state-law claims rest on the premise that the Evergreen Balloon Catheter should have been designed, manufactured, and labeled in a manner different than the one mandated by the FDA, those claims seek to impose state-law requirements "with respect to [the] device" that are "different from" and "in addition to" the device-specific "requirements" established by the FDA and are therefore preempted by Section 360k(a).

IV. PREEMPTION OF PETITIONER'S STATE-LAW CLAIMS FURTHERS THE OBJECTIVES OF THE MDA.

Through enactment of the MDA, Congress established a uniform federal regulatory framework designed to promote the development, production, and availability of safe and effective medical devices. Preemption of state common-law claims challenging the design, manufacturing, and labeling of PMA-

approved devices promotes this public-health objective by shielding device manufacturers from conflicting regulatory requirements and by preventing lay juries from second-guessing the FDA's expert decision-making through the imposition of potentially crippling state-law liability on manufacturers of devices that the FDA has found to be safe and effective.

A. In order to protect the public from unsafe and ineffective medical devices, the MDA established a comprehensive federal regulatory framework—one aspect of which is the requirement that those devices most likely to pose a risk to the public undergo the rigorous PMA process before reaching the market. At the same time, Congress recognized that imposing overly stringent and potentially conflicting regulatory requirements on the medical device industry could actually undermine the public health by reducing the number of commercially available medical devices. Congress therefore crafted the MDA to be a "balanced regulatory proposal" (H.R. Rep. No. 853, 94th Cong., 2d Sess. 12 (1976)) that promoted medical device safety while ensuring that innovation in the development of life-saving devices was not "stifled by unnecessary restrictions." *Id.* The statute "reflects the need to develop innovative new devices, consistent with the need to protect the subjects of device research." *Id.*

Congress's decision to include an express preemption provision in the MDA that extends beyond positive enactments to state common-law claims was an essential component of its effort to establish a uniform national regulatory framework favorable to technological innovation. As Congress recognized, subjecting manufacturers to a patchwork of overlapping and potentially inconsistent state-law requirements imposed on a case-by-case basis by lay juries

would substantially complicate manufacturers' efforts to develop new devices that complied with all applicable regulatory requirements. *See* H.R. Rep. No. 853, 94th Cong., 2d Sess. 45 (1976) ("[I]f a substantial number of differing requirements applicable to a medical device are imposed by jurisdictions other than the Federal government, interstate commerce would be unduly burdened.").

Indeed, this Court has observed that "the rules of law that judges and juries create or apply in [state common-law] suits may . . . create uncertainty and even conflict . . . when different juries in different States reach different decisions on similar facts." *Geier*, 529 U.S. at 871. Subjecting device manufacturers to conflicting state-law obligations would generate widespread regulatory confusion and frustrate attempts to bring new—and potentially life-saving devices—to the market. It is these precise considerations that prompted this Court to conclude that state-law fraud-on-the-FDA claims against medical device manufacturers are impliedly preempted. *See Buckman*, 531 U.S. at 350 ("complying with the FDA's detailed regulatory regime in the shadow of 50 States' tort regimes will dramatically increase the burdens facing" medical device manufacturers).

Far from promoting medical devices' safety and effectiveness, superimposing a layer of state-law regulation on top of the federal regulation of PMA-approved devices would actually imperil the public health. PMA-approved devices have been found to be safe and effective by the FDA based on its expert balancing of the risks and benefits presented by the device. 21 U.S.C. § 360c(a)(2)(C). If a jury is permitted to second-guess this expert regulatory judgment by imposing state-law liability based on the performance of a device designed, manufactured, and labeled in

conformity with its PMA requirements, the manufacturer will be placed in the untenable position of having to comply with inconsistent state and federal requirements. If the manufacturer continues to market its device without making alterations to correct the purported "defects" found by the jury, it will expose itself to additional state-law liability. On the other hand, if—to avoid state-law liability—the manufacturer alters the device's design, manufacturing, or labeling, the device will no longer meet the strict conditions of its PMA approval order, and the manufacturer will lack FDA authorization to distribute the modified product. The doctrine of federal preemption—and the MDA's express preemption clause, more specifically—are directed at precisely this type of intolerable conflict between state and federal law. *Cf. Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363, 378 (2000) (a state "statute conflicts with federal law" where it "penaliz[es] individuals and conduct that [the federal government] has explicitly exempted or excluded from sanctions").

Indeed, lay juries are singularly ill-equipped to evaluate the safety and effectiveness of medical devices, and, for that reason, Congress gave the FDA exclusive responsibility for making such determinations. When the FDA evaluates a device's safety and effectiveness, it takes a broad public health view, balancing not just the risks and benefits that would be experienced by a particular patient, but the risks and benefits that would be experienced by large classes of patients. A jury, in contrast, decides a particular case in isolation, without considering the wider policy implications of its decision. For example, although a jury would consider whether the warning that the plaintiff claims should have been included on a device's label would have prevented

the particular plaintiff's injury, the jury would not consider, and would have no basis for considering, whether inclusion of the warning would unduly detract from more important warnings or unnecessarily deter certain patients from using the device even though they might have benefited from it.[12]

Moreover, the imposition of state-law liability could deter the development of life-saving devices be-

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[12] Petitioner relies on *Bates* to suggest that lay juries should be allowed to nullify the FDA's expert determination that a medical device is safe and effective. *See* Pet. Br. 43. Petitioner's reliance on *Bates* is misplaced because the MDA's regulatory scheme is fundamentally different than the regulatory scheme established by FIFRA, the statute at issue in *Bates*. FIFRA, for example, requires that a pesticide be registered with the FDA before being sold, but "permit[s] the agency to register a pesticide without confirming the efficacy claims made on its label." *Bates*, 544 U.S. at 440. The EPA has "invoked this grant of permission and issued a general waiver of efficacy review." *Id.* As a result, the "EPA's approval of a pesticide label does not reflect any determination on the part of EPA that the pesticide will be efficacious." *Id.* (internal quotation marks omitted). It is therefore quite possibly true that, as *Bates* found, "[b]y encouraging plaintiffs to bring suit for injuries not previously recognized as traceable to pesticides," state-law tort claims "may aid in the exposure of new dangers associated with pesticides." *Id.* at 451 (internal quotation marks omitted). During the PMA process, in contrast, the FDA undertakes a rigorous review of a device's effectiveness (as well as its safety). FDA, Premarket Approval 1. Consequently, state-law tort actions are not necessary to uncover new dangers associated with medical devices. Moreover, the two statutes differ significantly in the role they accord state regulation. FIFRA "authorizes a relatively decentralized scheme that preserves a broad role for state regulation." *Bates*, 544 U.S. at 450. The MDA, however, does not preserve any "concurrent authority of the Federal and State Governments." *Id.* at 451. Indeed, "[u]nder the FDCA, . . . the FDA is vested with centralized authority in order to promote uniformity of regulation." U.S. Cert. Br. 16.

cause manufacturers might be reluctant to expend the necessary tens of millions of dollars in research-and-development funds where the introduction of a new device could potentially result in the imposition of untold amounts of state-law liability. Indeed, many Class III medical devices are invasive products that, in performing their life-saving function, expose patients to some inevitable degree of risk. For many such products, these risks can never be completely eliminated, no matter the rigor of the manufacturer's testing or the amount of resources devoted to research and development. These cutting-edge medical devices—like the Evergreen Balloon Catheter—nevertheless save hundreds of thousands of lives a year, and it is for this reason that the FDA, in its expert judgment, authorizes them to be marketed.

In determining whether to grant PMA approval, the FDA "weigh[s]" these "probable benefit[s] to health from the use of the device against [the] probable risk of injury or illness from such use." 21 U.S.C. § 360c(a)(2)(C). If the FDA determines that—notwithstanding the risks that the device may pose to a small number of patients—the device will be beneficial for the vast majority of patients, the FDA will find the requisite reasonable assurance of safety and effectiveness and will grant the device PMA approval. By definition, this "reasonable assurance" standard contemplates a balancing of risks and benefits to patients, and directly embraces the notion that such devices will not, even when PMA-approved, be *perfectly* safe and effective. Because the FDA's implementation of this careful balancing process cannot be replicated by lay juries, state court proceedings inevitably disrupt the FDA's risk-benefit analysis.

The American Medical Association has recognized the pernicious public-health consequences of

imposing state-law liability on manufacturers of complex medical devices, observing that:

> Product liability is having a profound negative impact on the development of new medical technologies. Innovative new products are not being developed or are being withheld from the market because of liability concerns or inability to obtain adequate insurance. Certain older technologies have been removed from the market, not because of sound scientific evidence indicating lack of safety or efficacy but because product liability suits have exposed manufacturers to unacceptable financial risks.

Am. Med. Ass'n, *Report of Board of Trustees: Impact of Product Liability on the Development of New Medical Technologies* 1 (1988); *see also* Am. Med. Ass'n, *House of Delegates: Proceedings* 59 (1991) ("The AMA has adopted policy supporting . . . efforts to prevent product liability suits from slowing the development and utilization of medical technologies.").

The important link between preemption protection and the public health is confirmed by the position of the FDA itself, which is entitled to substantial weight in determining the preemptive effect of agency action. *See Geier*, 529 U.S. at 883 ("The agency is likely to have a thorough understanding of its own regulation and its objectives and is 'uniquely qualified' to comprehend the likely impact of state requirements."). The FDA has repeatedly endorsed the position that the MDA preempts state common-law claims regarding PMA-approved devices. *See* Br. for the United States as *Amicus Curiae*, Horn v. Thoratec, 376 F.3d 163 (3d Cir. 2004) (No. 02-4597);

U.S. Cert. Br. 2-3. According to the FDA, exposing manufacturers of PMA-approved devices to state-law liability would "undermine overall public health protection" by interfering with the FDA's expert evaluation of the safety and effectiveness of those devices, by "retarding research and development," and by "encouraging 'defensive labeling' by manufacturers to avoid state liability, resulting in scientifically unsubstantiated warnings and underutilization of beneficial treatments." U.S. *Horn* Br. 3, 26.

Because the imposition of state-law liability on manufacturers of PMA-approved medical devices could decrease the availability of these life-saving devices, it is those patients dependent on such devices for life-sustaining treatment who would suffer most greatly from the distorting effects of unnecessary state regulation.

B. Petitioner's countervailing contention that PMA preemption leaves plaintiffs injured by Class III devices without a remedy is vastly overstated.

First, as the Second Circuit observed, the number of medical devices introduced via the PMA process each year is exceedingly small. Pet. App. 36a. Indeed, in fiscal year 2005, the FDA received 3130 § 510(k) notifications, but only 43 original PMA applications. *See* FDA, 2005 Annual Report 26. Thus, nearly 99% of new Class III medical devices reached the market via the § 510(k) notification process—and that process, this Court concluded in *Lohr*, does not preempt state-law claims. Second, state-law claims based on parallel state-law requirements that are neither "different from" nor "in addition to" those established by the PMA process are not preempted by Section 360k(a), which leaves potential plaintiffs with a state-law remedy for negligent manufacturing

and breach of express warranty, where appropriate. *Lohr*, 518 U.S. at 495. Third, petitioner overlooks the fact that the preemptive effect of the PMA process enhances the safety of medical devices—and reduces the likelihood of personal injury—by affording manufacturers an incentive to subject their products to the rigorous safety-and-effectiveness examination of the PMA process, rather than the substantially more relaxed review of the § 510(k) notification process. If PMA-approved devices became subject to a wide array of state-law products liability claims, there would be substantially less reason for a manufacturer to undertake the costly and time-consuming PMA process for devices that could be cleared pursuant to § 510(k) review.

Preemption of this limited class of claims is thus not only consistent with the MDA's objectives—it is essential to securing the statute's public-health goals.

CONCLUSION

The judgment of the court of appeals should be affirmed.

Respectfully submitted.

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